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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,062	03/09/2005	Andrea Giori	2503-1113	1372
<div>465 7590 08/12/2008</div> <div>YOUNG & THOMPSON</div> <div>209 Madison Street</div> <div>Suite 500</div> <div>ALEXANDRIA, VA 22314</div>				
EXAMINER				
PRATT, HELEN F				
ART UNIT		PAPER NUMBER		
1794				
MAIL DATE		DELIVERY MODE		
08/12/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,062

Applicant(s)

GIORI, ANDREA

Examiner

Helen F. Pratt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 9-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is indefinite in the use of the phrase "tomato whole extracts". It is not known what is meant by this phrase.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ausich et al. (5,858,700) in view of Kagan (US 2003/0044495) and Schaap (WO 03/08064).

Ausich et al. disclose a process of making a tomato paste made by the claimed steps as in 1a and b of pretreating and heat concentrating tomatoes. The composition is then freeze dried and extracted with hexanes and the extracts were concentrated to make a tomato paste oleoresin containing lycopene. The composition is then saponified, then the composition is treated with water to disperse the reaction products and other impurities, and then filtered and lycopene crystals are recovered (col. 11, lines

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60-70, col. 12, lines 1-60). The amount of lycopene is seen to have been within the disclosed range (col. 12, lines 46-60). The particular amount of reducing sugars is seen to be less than 1% since the lycopene paste oleoresin has been washed and reducing sugars are water soluble and would have been removed from the extract. The use of ethyl acetate is disclosed in col. 6, lines 55-58 as a possible solvent. However, the reference uses other solvents mainly because they are less toxic (col. 7, lines 12-40). Claim 1 differs from the reference in that the ethyl acetate is water-saturated . However, no difference is seen in the use of water-saturated ethyl acetate and ethyl acetate absent a showing of unexpected results using the water-saturated ethyl acetate. It would have been obvious to substitute other solvents for the claimed solvent because the number of solvents available are limited, and it would have taken only routine experimentation to arrive at the most effective solvent. In addition, Schaap discloses that ethyl acetate is known as a solvent (page 30, lines 9-11) and nothing is seen in using water-saturated ethyl acetate absent a showing of unexpected results. Kagan et al. disclose the use of water and ethyl acetate as solvents in extraction of carotenoids and lycopene (abstract and 0029, 0030, 0034, 0038). No patentable distinction is seen at this time in the use of water and ethyl acetate and in a hydrated ethyl acetate. Therefore, it would have been obvious to substitute the ethyl acetate of Schaap and the water-ethyl acetate mixture of Kagan in the process of Ausich et al. for its known function of being a solvent and to use a hydrated source of the solvent since Kagan et al. disclose the use of water and ethyl acetate as solvents in extraction of carotenoids.

Ausich et al. disclose a composition as in claim 5 containing from 90.6-89.6% total carotenoid analyzed as lycopene made from tomato paste (col. 12, lines 46-60). Claim 5 differs from the reference in the use of the process of claim 1. Claim 5 is also a product by process claim. The fact that the procedures of the reference are different than that of applicant is not a sufficient reason for allowing the product-by-process claims since the patentability of such claims is based upon the product formed and not the method by which it was produced. See *In re Thorpe* 227 USPQ 964. The burden is upon applicant to submit objective evidence to support their position as to the product-by-process claims. See *Ex parte Jungfer* 18 USPQ 2D 1796. Therefore, it would have been obvious to make a composition containing the claimed lycopene with low reducing sugars as shown by the combined references.

Claims 9--17 are to further processing limitations which would have been within the skill of the ordinary worker to adjust. Therefore, it would have been obvious to use normal processing conditions to make the claimed product.

It is proposed that if applicants limited their claims to "consisting of", this would eliminate the references which have additional processing steps than those claimed. Also, the product claim should be cancelled since it has been disclosed by the combination of the references and no difference is seen at this time in the products because they are now extracts.

Claim 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ausich et al. as above as applied to claims 1, 5, 9-17 above, and further in view of Bombardelli et al. (EP 0818 225).

Claim 2 further requires concentrating the extract, filtering and drying the lycopene. Ausich et al. disclose that it is known to concentrate hexane extracts under vacuum to produce lycopene containing oleoresins (col. 13, lines 19-30). Even though the lycopene was taken from the dried skin, it would have been obvious to concentrate any tomato composition in order to remove excess liquid. Filtering and drying is disclosed in col. 13, lines 45-55. Adding oil is disclosed by Bombardelli et al. (page 5, lines 20-35). Also, an oleoresin by definition is oil and a resin. Nothing new is seen in the use of "seed oil", as most oils are from seeds as in corn oil, flax seed oil, olive oil. Schaap et al. disclose that it is known to use ethyl acetate as a solvent when washing crystalline carotenoids (page 30, lines 8-15). The reference also discloses that it is known to wash the crystalline carotenoid suspension (page 30, lines 10-29). The biomass is used to produce lycopene (abstract). Therefore, it would have been obvious to treat lycopene containing ingredients as disclosed by Ausich et al., and to add oil to the resin product to make an oleoresin, using known oils and to use ethyl acetate as a solvent as shown by Schaap and Kagan et al. and to further wash the composition in an aqueous solution as shown by Schaap in order to make a lycopene composition.

Nothing new is seen in using oil from the tomato seed, absent anything new or unobvious as in claim 3 or in the use of soybean oil, as the reference to Bombardelli et

al. use vegetable oil in general, and it would have been obvious to choose an oil which was compatible with the oleoresin in taste.

ARUGUMENTS

Applicant's arguments filed 5-29-08 have been fully considered but they are not persuasive. Applicants argue that Ausich et al.s' starting material is an oleoresin and that the skins, paste and pomace can be used to make the oleoresin and that hexanes are the preferred solvents and that the present invention uses "fresh tomatoes". It is not seen how using all these forms differ from using a whole tomato, except for the water content, which does not affect the extraction of lycopene especially as the fresh tomato is heat concentrated, which is how tomato paste is made. Also, the reference discloses the use of ethyl acetate, but doesn't say that it is water saturated. It is not known what the difference would have been in using water saturated ethyl acetate. At any rate, the reference to Kagan was used to show that water and ethyl acetate can be used together in an extraction process.

It is not seen how Ausich et al. can be non-analogous art when Ausich et al. extracts from tomato ingredients.

Applicants argue that the lycopene paste oleoresin of Ausich has been "washed", but this is not using whole tomatoes. However, by the time applicants tomatoes are heat concentrated, they will be in paste form too. The extract, i. e. collected crystals in Ausich are washed extensively to remove residual contaminants, (col. 9, lines 22-30). Applicants' claim does not say how much washing is required except to have reducing sugars content expressed as 1%. Certainly the process of Ausich which extensively

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washes the crystals and before that has a saponification steep, would have sugars within the claimed range. In addition, removing sugars with water is not unexpected or unobvious since sugars are soluble in water and easy to remove.

Schaap et al. was used for the teaching that it is known to use ethyl acetate as a solvent, and not for the whole process. The further solvents of Kagan have not been excluded from the claims and Kagan also was used for a particular teaching as in the office action.

Applicants have not excluded the other steps of the above references, particularly Ausich et al. from instant claims as in using "consisting of".

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 571-272-1404. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Helen F. Pratt/

Primary Examiner, Art Unit 1794